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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,025	06/17/2001	Gilad Lavi	01.EMT46.US	9705

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EXAMINER
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AHMED, AAMER S

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/883,025

Applicant(s)

LAVI ET AL.

Examiner

Aamer S. Ahmed

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 17-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-16 and 28-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/12/2002.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Claim 13 is written as depending from claim 11 or 12. Since applicant has withdrawn claim 12 as pertaining to a non-elected species, claim 13 should be rewritten to depend from claim 11 only.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Bachynsky U.S. Patent Number 5,267,963. Bachynsky ('963) discloses a needle device (10) comprising a housing (20) having a base (19) adapted to be placed next to a surface of a needle penetrating site, the base (19) including an opening (18); a needle (12) mounted for a movement between a retracted position in the housing (20) and an extended position, where a portion of the needle (12) extends through the opening (18) when in the extended position; an actuator (11)

movably mounted to the housing (20) and movable between an unactuated position at which the needle (12) is in the retracted position and an unactuated position at which the needle (12) is in the extended position, the actuator being biased toward the unactuated position; a retraction mechanism (4, 5) that automatically moves the needle (12) from the extended position to the retracted position upon releasing the base (19) from the site surface; wherein the retraction mechanism (4, 5) maintains the needle (12) in the retracted position upon moving the actuator (11) to the actuated position; and wherein the device (10) further comprises a locking mechanism (16) that prevents the needle (12) from moving back to the extended position once the needle (12) has been moved from the extended position to the retracted position, and is integral with the retraction mechanism (4, 5) (see figures 1a, 3 and col. 3 line 45).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-7 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky ('963) in view of Richard U.S. Patent 5,201,716. Bachynsky discloses the needle device as described above in references to claims 1 and 28. Furthermore Bachynsky ('963) discloses that the device (10) has a trigger member (4) movably mounted to the housing (20), the trigger member (4) having a first portion adapted to engage the actuator (11); wherein the trigger member (4) is pivotally mounted to the housing (20); and wherein the housing (20) has an actuator guide (8) that guides the actuator (11) through a predetermined path of movement, see figures 1a and 3.

Bachynsky ('963) fails to disclose that the trigger member has a second portion adapted to contract the site surface; that the base includes a second opening through which the second portion of the trigger member is adapted to contact the surface nor that the retraction mechanism includes a cover member for covering the opening after the needle moves from the extended to the retracted position.

Richard ('716) discloses a similar needle device in which that the trigger member (58) has a second portion (62) adapted to contact the site surface; that the base (72) includes a second opening (see figure 2) through which the second portion of the trigger member (62) is adapted to contact the surface and that the retraction mechanism includes a cover member (70) for covering the opening after the needle moves from the extended to the retracted position, see figure 3.

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the needle device of Bachynsky ('963) by adapting the trigger portion to contract the site surface, to add a cover member and a second base opening as taught by

Richard ('716) in order to so that the assembly can be used without being touched by human hands, thereby minimizing a health worker's exposure to contaminated needles (Richard '716 col. 7, line 52).

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky ('963) and Richard ('716) and further in view of Wozencroft WO 93/01851. Bachynsky ('963) and Richard ('716) disclose a needle device as described above in reference to claim 7. Neither Bachynsky ('963) nor Richard ('716) disclose that the guide comprises a substantially U-shaped channel formed in the housing nor that the device includes a pin adapted to be guided in the U-shaped channel.

Wozencroft ('851) discloses a similar needle device in which the guide (131) comprises a substantially U-shaped channel, (see figure 11) formed in the housing (106), the U-shaped channel comprising a first substantially vertical portion (132), a second substantially vertical guide portion (131) and a horizontal guide portion (between 131 and 132) connecting lower ends of the first and second vertical portions, see figure 11; and a pin (114) adapted to be guided in the U-shaped channel.

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the needle device of Bachynsky ('963) and Richard ('716) by adding a substantially U-shaped channel and a pin adapted to be guided in the U-shaped channel as taught by Wozencroft ('851) in order to control of the needle in a predetermined way (Wozencroft '851 p13 line 22).

Claims 10, 11 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky ('963), Richard ('716) and Wozencroft ('851) and further in view of Miskinyar U.S. Patent Number 4,894,054.

As to claims 10 and 11, Bachynsky ('963), Richard ('716) and Wozencroft ('851) disclose a needle device as described above in reference to claim 9. Furthermore, Bachynsky ('963) discloses a spring (9) and Wozencroft ('851) discloses that the spring is fixedly mounted to the actuator (11) and is torsionally preloaded to rotate the actuator (117) from the first vertical guide portion to the second vertical portion upon moving the actuator (117) to the actuated position. Bachynsky ('963), Richard ('716), Wozencroft ('851) and Miskinyar ('054) disclose a needle device as described above in reference to claim 11. Furthermore, Wozencroft ('851) discloses that the device includes a trigger member (118) pivotally mounted in the housing (101) and the first portion thereof adapted to engaged the pin (114) and prevent the actuator from moving to the unactuated position when the pin (114) is positioned in the second vertical guide position (131), and wherein the guide further includes a lock portion (131). Richard discloses that a portion of the trigger member and the second portion of the trigger member (62) is adapted to contact the surface and that the base (72) includes a second opening (see figure 2) through which the second portion of the trigger member (62) is adapted to contact the surface.

Neither Bachynsky ('963), Richard ('761) nor Wozencroft ('851) discloses that one end of the spring is mounted to the base to enable creation of a spring torsional load when the actuator is rotated relative to the base.

Miskinyar ('054) discloses a similar needle device with one end of the spring (102) is mounted to the base to enable creation of a spring torsional load when the actuator is rotated relative to the base, see figure 8.

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the needle device of Bachynsky ('963), Richard ('716) and Wozencroft ('851) by mounting the other end of the spring to the base as taught by Miskinyar ('054) in order to ensure that the medication is not prematurely ejected from the ampoule chamber (col. 5 line 19).

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5931814 A	Alex; Rainer et al.
US 5672161 A	Allen; William J. et al.
US 6149626 A	Bachynsky; Nicholas et al.
US 5885257 A	Badger; Peter
US 4231368 A	Becker; Michael
US 20040162521 A1	Bengtsson, Henrik
US 5429612 A	Berthier; Michel
US 20030225373 A1	Bobroff, Randa M. et al.
US 6638248 B1	Brewer; Roy Tudor
US 6001089 A	Burroughs; Andrew et al.
US 5487733 A	Caizza; Richard J. et al.
US 5295971 A	Cameron; Donald
US 6676669 B2	Charles; Steve T. et al.
US 4886499 A	Cirelli; Giorgio et al.
US 5848990 A	Cirelli; Giorgio et al.
US 5356383 A	Daly; Eugene et al.
US 4512767 A	Denance; Raymond
US 5034003 A	Denance; Raymond
US 5891093 A	Dysarz; Edward D.
US 5935113 A	Dysarz; Edward D.
US 4340048 A	Eckenhoff; James B.
US 5167632 A	Eid; J. Francois et al.



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US 6290683 B1	Erez; Uri et al.
US 6093172 A	Funderburk; Jeffery V. et al.
US 20010025168 A1	Gross, Joseph et al.
US 6595956 B1	Gross; Joseph et al.
US 4067334 A	Haller; J. Gilbert
US 4198975 A	Haller; J. Gilbert
US 6264637 B1	Hogan; Thomas
US 6083237 A	Huitema; Thomas W. et al.
US 6796967 B2	Jensen; James U.
US 4850973 A	Jordan; Pavel et al.
US 4858607 A	Jordan; Pavel et al.
US 4966589 A	Kaufman; Jerry M.
US 5024665 A	Kaufman; Jerry M.
US 20040225281 A1	Lorenzen, Eric et al.
US 5891105 A	Mahurkar; Sakharam D.
US 5836911 A	Marzynski; Matthew et al.
US 4442836 A	Meinecke; Dieter et al.
US 5453092 A	Merriman; Grant B.
US 6830562 B2	Mogensen; Lasse Wesseltot et al.
US 4270537 A	Romaine; Richard A.
US 20030130619 A1	Safabash, Jason H. et al.
US 6293925 B1	Safabash; Jason H. et al.
US 20040059316 A1	Smedegaard, Jorgen K.
US 6666100 B1	Snyder; Philip A.
US 3702609 A	Steiner; Maurice
US 5637094 A	Stewart, Jr.; Edward et al.
US 4781688 A	Thoma; Herwig et al.
US 6447527 B1	Thompson; Ronald J. et al.
US 6254575 B1	Thorne, Jr.; Gale H. et al.
US 5858001 A	Tsals; Izrail et al.
US 4261358 A	Vargas; Walter et al.
US 6056728 A	von Schuckmann; Alfred
US 5591188 A	Waisman; Marc
US 4227528 A	Wardlaw; Stephen C.
US 6149629 A	Wilson; Michael A. et al.
US 5520650 A	Zadini; Filiberto et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.A.



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